REMARKS

This Amendment is responsive to the Office Action dated May 18, 2007. Applicant has amended claims 20, 23-26, 29, 32-35, 37, 40, 42, 43, 64-66, 68, 69, and 74-76, and canceled claims 22, 31, 41, and 67. Claims 20, 21, 23-30, 32-40, 42-45, 60-66, and 68-76 are pending.

Information Disclosure Statement

The Office Action indicated that the Information Disclosure Statement (IDS) filed on March 11, 2004 fails to comply with the provisions of 37 C.F.R. 1.97, 1.98, and MPEP 609 because several of the references lack a date of publication. With the present Amendment, Applicant submits a Supplemental IDS that includes dates for the relevant publications. Applicant respectfully submits that the attached Supplemental IDS complies with 37 C.F.R. 1.97, 1.98, and MPEP 609, and respectfully requests consideration of the references cited therein.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, claims 29-45 and 69-76 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Office Action found that in claim 29, the "implantable neurostimulator" and "at least one user-chosen criteria" are inferentially recited. While Applicant does not agree with the Office Action's conclusion of indefiniteness, Applicant has amended claim 29 for purposes of clarification.

The Office Action also objected to claim 29 on the basis that the reference to "a plurality of stimulation settings" was inferential. Applicant respectfully disagrees. As provided by M.P.E.P 2173.05(g), devices may be defined in terms of the functions they perform, so long as the claim language sets boundaries on the patent protection sought. Claim 29 recites a device that is adapted to control an implantable neurostimulator to deliver neurostimulation to a patient according to a plurality of stimulation settings. Regardless of where the stimulation settings are stored, the function of the device remains clear and claim 29 clearly sets boundaries on the patent protection sought. Accordingly, Applicant believes claim 29 particularly point out and distinctly claims the subject matter which Applicant regards as the invention.

With respect to the rejection of claims 37, 40, and 69 under 35 U.S.C. § 112, second paragraph, Applicant has amended claims 37, 40, and 69 for purposes of clarification. Applicant submits that claims 29-45 and 69-76, as amended, particularly point out and distinctly claim the subject matter, as required by 35 U.S.C. 112, second paragraph. Reconsideration and withdrawal of the rejection of claims 29-45 and 69-76 under 35 U.S.C. § 112 is respectfully requested.

Claim Rejection Under 35 U.S.C. §§ 102(e) and 103(a)

In the Office Action, claims 20-24, 26-33, 36-38, 40-42, 44, 45, 63, 67, 68, 73, 75 and 76 were rejected under 35 U.S.C. § 102(e) as being anticipated by Torgerson et al. (U.S. Patent No. 5,893,883, "Torgerson"). In addition, claims 20-45, 63-68 and 73-76 were rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Law et al. (U.S. Patent No. 5,938,690, "Law"). Claims 28, 37 and 45 were rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Law or Torgerson, and claims 60-62 and 69-72 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Law or Torgerson in view of Fowler et al. (U.S. Patent No. 5,370,672, "Fowler").

Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. §§ 102(e) and 103(a), and provides no teaching that would have suggested the desirability of modification to include such features.

Independent claims 20, 29, and 40

For example, the applied references fail to teach or suggest a method that includes collecting multiple types of information for a plurality of stimulation settings and ordering the list according to at least one user-chosen criteria selected from the collected information, as recited by Applicant's claim 20 as amended. Claim 20 recites, among other things, collecting information for each of a plurality of stimulation settings, where the information comprises a threshold amplitude for a particular stimulation setting, and rating information, which includes a

numeric rating for the particular stimulation setting and a degree of overlap between a paresthesia map for the particular stimulation setting and a pain map.

As the Office Action recognized, Torgerson discloses collecting numerical rating information for a set of stimulation parameters,[1] and Law discloses comparing a stimulation map to a patient map.[2] However, neither reference contemplates collecting <u>multiple</u> types of information, including rating information and threshold amplitude information, and ordering a list of stimulation settings according to a criteria <u>selected by a user</u> from the collected ˙ information. In fact, as described in further detail below, Law does not even contemplate ordering a list of stimulation settings according to a user-chosen criteria.

Furthermore, even if the disclosures of Torgerson and Law were combined, each and every element of Applicant's independent claim 20 would not be disclosed or suggested. While Applicant disagrees that there is a motivation to combine Torgerson and Law, even the combined references would lack a disclosure or suggestion to collect a threshold amplitude value for each of a plurality of stimulation settings, collect rating information, and order the list of stimulation settings according to at least one criteria selected by a user from collected information that includes rating information and the threshold amplitude value for each stimulation setting. Torgerson does not contemplate providing a user with an option to order stimulation settings by anything other than numerical rating information, and certainly does not provide a user with the option of choosing a criteria by which to order stimulation settings, as recited in Applicant's claim 20. Law also fails to contemplate ordering a list of the stimulation settings according to at least one user-chosen criteria.

In support of the rejection of claim 20, the Office Action found that the Abstract and column 7, lines 30-60 of Law disclose a method that includes displaying a list of stimulation settings, and that column 12, lines 15-30 and column 14, lines 1-15 disclose ordering the list according to a user chosen criteria, such as a paresthesia map drawing.[3] The Office Action reasoned that Law teaches a method that includes ordering the list because "other settings are

---

[1] Torgerson at col. 9, ll. 13-30.
[2] Law at col. 12, ll. 14-15.
[3] Office Action at page 4.

eliminated" or "a score is given to the setting for evaluation to determine the most effective setting."[4]

Contrary to the Office Action's assertion, Law does not teach a method that includes ordering a list of stimulation settings according to a user chosen criteria. Neither the column 12, lines 15-30 nor column 14, lines 1-15 support such an assertion. Instead, at the portions of Law cited by the Office Action, Law only discloses a Stimulation Test Results screen that presents stimulation settings and results of testing, and a stimulation map that may be used to determine a "relative score" of an electrode combination for later qualitative analysis. Law does not indicate that in the Stimulation Test Results screen, the list is <u>ordered</u> according to at least one <u>user-chosen criteria</u>, as required by Applicant's independent claim 20. According to the method recited in Applicant's claim 20, a user is able to interact with a list of stimulation settings by selecting a criteria from collected information. A list of stimulation settings may be ordered according to the user-chosen criteria. Law does not disclose or suggest such a method. Instead, the Stimulation Test Result screen described by Law is merely that, a screen that conveys "the date of stimulation; the stimulation setting . . .; the perception, bilateral and motor thresholds; and various assessment ratios."[5] Law does not disclose or suggest that the list may be ordered, much less ordered according to a user-chosen criteria.

The Office Action appears to be relying on an improper finding of inherent disclosure in Law to support the rejection of the claims. The fact that a certain characteristic may be present in the prior art is not sufficient to establish the inherency of that result or characteristic.[6] The Office Action must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic <u>necessarily</u> flows from the teachings of the applied prior art.[7] No reasonable support has been provided for the determination that Law <u>necessarily</u> orders a list of stimulation settings according to at least one user-chosen criteria. Rather, in view of the lack of description provided by Law, it is possible that the Stimulation Test Results screen of Law merely displays the stimulation settings and results of testing without

---

[4] *Id.*
[5] Law at col. 10, ll. 27-34.
[6] *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ.2d 1955, 1957 (Fed. Cir. 1993); MPEP 2112.
[7] *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112.

any particular order to the stimulation settings. Accordingly, Applicant submits that the allegedly inherent characteristic does not necessarily flow from the teachings of Law.

The Office Action offered an alternative rejection of claim 20 in view of Law. In particular, the Office Action conceded that Law does not disclose ordering a list of stimulation settings according to numeric rating information.[8] In order to support the obviousness rejection of Applicant's claim 20, however, the Office Action found that it would have been obvious to one having ordinary skill in the art at the time the invention was made to order the list according to numeric rating information because "ordering the list according to numeric rating information [allows] a comparison between the results to provide the most effective stimulation setting to the patient."[9] Applicant respectfully disagrees. Law discloses evaluating the efficacy of a stimulation setting "by the percentage of overlap of the stimulation map and pain map."[10] Based on this disclosure in Law, it is unclear why one skilled in the art would have been motivated to compare numeric rating information or collect other types of information (e.g., amplitude thresholds) and order a list of stimulation settings according to a criteria selected by a user from among the collected information. Law only teaches consideration of a single metric, .e., percentage overlap, for evaluating the efficacy of a stimulation setting. Accordingly, it is unclear how Law could possibly suggest ordering a list according to user-chosen criteria.

Furthermore, even if one skilled in the art would have been motivated to compare numeric rating information based on the disclosure in Law, which Applicant disagrees with, a comparison of numeric rating information does not necessarily require an ordering of a list of stimulation settings according to at least one user-chosen criteria that is selected from rating information and threshold amplitudes, as recited by independent claim 20. A list of stimulation settings that is not ordered according to a user-chosen criteria would also support a comparison between stimulation settings. Thus, the motivation proposed by the Office Action does not necessarily provide the proper motivation for modifying the Law method to arrive at Applicant's claimed invention.

The conclusion of obviousness advanced by the Office Action appears to rely on a motivation plucked directly from Applicant's own disclosure, rather than the prior art. The

---

[8] Office Action at page 5.
[9] *Id.*
[10] Law at col. 11, ll. 54-64.

Office Action cited no prior art teaching as the source for the alleged motivation to modify Law. It is improper for the Office Action to rely on unsupported, conclusory statements to close holes in the evidentiary record.[11] Neither Law nor Torgerson even contemplate ordering a list according to a user-chosen criteria, much less provide a motivation for doing so. Accordingly, unless the Office Action can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill in the art to order a list of stimulation settings according to at least one user-chosen criteria, independent claim 20 should be allowed.

Applicant's independent claim 29 recites a device adapted to control an implantable neurostimulator to deliver neurostimulation to a patient according to a plurality of stimulation settings during a programming session, display a list of the stimulation settings via a display, collect information for each of the stimulation settings, receive input from a user selecting at least one criteria selected from the collected information, and order the list according to the at least one criteria. According to claim 29, the collected information comprises rating information that includes a numeric rating for each of the stimulation settings and a degree of overlap between a paresthesia map for the stimulation setting and a pain map, and a threshold amplitude value for the stimulation setting. For similar reasons described above with respect to independent claim 20, neither Law nor Torgerson disclose or suggest each and every element of independent claim 29. For example, the Law device is not adapted to receive input from a user selecting at least one criteria selected from the collected information, nor order a list of stimulation settings according to the selected criteria.

Similarly, the applied references fail to disclose or suggest each and every element of Applicant's independent claim 40. Claim 40 recites a system that includes, among other things, means for controlling an implantable neurostimulator to deliver neurostimulation to a patient according to a plurality of stimulation settings during a programming session, means for collecting information for each of the stimulation settings, and means for ordering the list according to at least one user-chosen criteria selected from the collected information. The information comprises a threshold amplitude value for the stimulation setting and rating

---

[11] *In re Lee*, 61 USPQ2d 1430, 1434 (Fed. Cir. 2002).

information comprising a numeric rating for the stimulation setting and a degree of overlap between a paresthesia map for the stimulation setting and a pain map.

The cited references fail to disclose or suggest each and every limitation set forth in Applicant's independent claims 20, 29, and 40. For at least these reasons, the Office Action has failed to establish a prima facie case of nonpatentability of claims 20, 29, and 40 under 35 U.S.C. §§ 102(e) and 103(a). Reconsideration and withdrawal of the rejection of the claims is respectfully requested.

Dependent Claims

Claims 21, 23-28, 60-66, and 68 depend from claim 20, claims 30, 32-39, and 69-75 depend from claim 29, and claims 42-45 and 76 depend from claim 40. As established above, independent claims 20, 29, and 40 are patentable over the cited references, and as a result, all claims depending therefrom are also patentable over the cited references. Applicant also traverses the rejections of the dependent claims. The prior art of record fails to teach each and every element of the dependent claims, and the rejection should be withdrawn. Applicant addresses some of the dependent claims below for purposes of illustration.

Claim 60 depends from claim 20 and recites a method that includes storing a plurality of predetermined programming codes, identifying a type of an implantable neurostimulator, selecting one of the plurality of programming codes based on the identified type, and transmitting the selected programming code to the implantable neurostimulator to enable programming of the implantable neurostimulator. Claim 69 depends from claim 29 and is directed to a device that includes an antenna that identifies a type of implantable neurostimulator, and a transmitter interface that includes a memory to store a plurality of predetermined programming codes, where the transmitter interface is adapted to receive an indication of the identified type of the implantable neurostimulator, select one of the plurality of programming codes based on the identified type, and transmit the selected programming code to the implantable neurostimulator via the antenna to enable programming of the implantable neurostimulator to deliver neurostimulation to the patient.

The Office Action rejected claims 60 and 69 as being unpatentable over Law or Torgerson in view of Fowler. While recognizing that neither Law nor Torgerson disclose each

-17-

and every element of claims 60 and 69, the Office Action reasoned that "Fowler teaches that it is known to use an IBM computer, with transmitter and antenna and would necessarily store the programming codes, identify a type of neurostimulator, select a programming code based on the neurostimulator, and transmit the code to the stimulator . . . to allow the system to work with several different types of neurostimulators."[12] However, the Office Action offered no support found within the cited references for the conclusion that Fowler <u>necessarily</u> stores the programming codes, identifies a type of neurostimulator, and so forth.

Fowler does not describe an interface that is compatible with different types of implant devices. Rather, Fowler only states that "we have developed an interface from an IBM personal computer to several commercially available RF transmitters."[13] Nothing in Fowler indicates that the same IBM computer or the same interface is necessarily intended to work with different types of neurostimulators. Even if Fowler discloses a device that is intended to work with different types of neurostimulators, nothing in Fowler indicates that the device necessarily includes each and every limitation of claims 60 and 69.

The Office Action appears to be relying on an improper finding of an inherent disclosure in Fowler. As previously described, the Office Action must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic <u>necessarily</u> flows from the teachings of the applied prior art.[14] None of the cited references provided by the Office Action provide any basis for indicating that the Fowler device <u>necessarily</u> stores a plurality of predetermined programming codes, much less identifies a type of an implantable neurostimulator, as required by claim 60, or includes a transmitter interface that is adapted to receive an indication of the identified type of the neurostimulator, select one of a plurality of programming codes based on the identified type, and transmit the selected programming code to the neurostimulator via an antenna, as required by claim 69.

The Office Action also found that the Fowler device necessarily transmits the programming code to the neurostimulator by modulating a carrier signal. Again, the Office Action offers absolutely no support for this assertion that Fowler necessarily modulates a carrier signal, and accordingly, Fowler cannot disclose each element of Applicant's claim 61.

---

[12] Office Action at pages 6-7.
[13] Fowler at col. 2, ll. 46-49.
[14] *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original); MPEP 2112.

With respect to dependent claim 66, the Office Action found that at column 8, lines 35-70, Law discloses determining whether an amplitude falls within boundaries, and, therefore, anticipates claim 66. Applicant respectfully disagrees. Claim 66 recites a method that includes determining whether rating information for each stimulation setting falls within boundaries based on a threshold amplitude value. At column 8, lines 35-70, Law merely discloses that "[a]s a means of evaluating the symmetry of the stimulation, the computer system compares the ratio of the bilateral threshold to the perception threshold."[15] Neither this disclosure in Law nor any other disclosure in law relates to or even contemplates determining whether rating information for a stimulation setting falls within boundaries that are based on a threshold amplitude value. It is unclear how evaluating symmetry of stimulation constitutes rating information for a stimulation setting. Law does not even state that the threshold ratio is compared to boundaries that are based on a threshold amplitude value. Accordingly, it is unclear how Law teaches the elements of claim 66.

For at least these reasons, the cited references fail to teach or suggest each and every element of Applicant's dependent claims 21, 23-28, 30, 32-39, 42-45, 60-66, and 68-76. Reconsideration and withdrawal of the rejection of the claims is respectfully requested.

Rejection for Obviousness-type Double Patenting

The Office Action rejected claims 20-45 and 60-76 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,308,102 in view of Law or Torgerson and Fowler. Applicant respectfully traverses this rejection. Applicant respectfully submits that the Office Action has not established a prima facie case of obviousness-type double patenting, and that the pending claims would not have been obvious in view of the claim 1 or any of the other claims of U.S. Patent No. 6,308,102 in view of Law or Torgerson and Fowler.

---

[15] Emphasis added.

To support an obviousness-type double patenting rejection, the Office Action must assess the differences between the claims in the pending application and the claims in the issued patent.[16] However, Office Action merely asserted that "[t]he patented claims are narrow and meet the limitations of the broader application claims" and generally reasoned that, "it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the patented claims the ordering, maps, transmitter, etc in view of Law or Torgerson and Fowler . . . since it provides a stimulation system and method that can choose the most effective stimulation pattern to apply to the patient using a single programming device."[17] Applicant respectfully disagrees with the Office Action's analysis.

As established above, Law, Torgerson, and Fowler fail to disclose or suggest each and every element of Applicant's claims. Furthermore, it is unclear how the claims 1-37 of U.S. Patent No. 6,308,102 are "narrow" and "meet the limitations" of Applicant's claims. For example, claim 1 of U.S. Patent No. 6,308,102 recites:

> 1.   In a patient interactive neurostimulation system, including processing means accepting the patient entered data and patient interactive means for direct interaction between the patient and said processing means, said patient interactive means being used for patient data entry, wherein an improvement comprises:
>   means for presetting consistency boundaries for data entered by the patient into said processing means by means of said patient interactive means,
>   checking means for verifying whether said entered data falls within said consistency boundaries, and
>   means for repeating said data entry by said patient when said entered data fails to fall within said consistency boundaries.

In contrast, Applicant's claim 20 relates generally to controlling an implantable neurostimulator to deliver neurostimulation to a patient according to a plurality of stimulation settings during a programming session, collecting information for each of the stimulation settings, and ordering the list according to at least one user-chosen criteria selected from the collected information. Nothing in claim 1 of U.S. Patent No. 6,308,102 even recites controlling an implantable neurostimulator to deliver neurostimulation to a patient according to a plurality of stimulation settings, displaying a list of the stimulation settings or ordering the list according to at least one user-chosen criteria, as recited in Applicant's claim 20.

---

[16] *In re Berg*, 46 USPQ.2d 1226, 1229 (Fed. Cir. 1998).
[17] Office Action at page 8.

One skilled in the art at the time of the invention would not have been motivated to look to Law or Torgerson and Fowler to modify claim 1 of U.S. Patent No. 6,308,102. The proposed motivation of providing a stimulation system and method that can choose the most effective stimulation pattern to apply to the patient using a single programming device is irrelevant, particularly because the language of claim 1 of U.S. Patent No. 6,308,102 does not recite selecting an effective stimulation pattern.

M.P.E.P. 804 provides guidance as to when an obviousness-type double patenting rejection is appropriate. According to M.P.E.P. 804, the rejection is appropriate when a claim in the application defines an invention that is merely an obvious variation of an invention claimed in the patent. It is unclear how Applicant's claim 20, which does not recite consistency boundaries, is an obvious variation of claim 1 of U.S. Patent No. 6,308,102, even if view of Law or Torgerson and Fowler.

The rejection for obviousness-type double patenting should be withdrawn. If the Office Action chooses to maintain the obviousness-type double patenting rejection, however, Applicants respectfully request clarification of the grounds of rejection.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: By:

August 16, 2007   _Jessica H Kwak._
SHUMAKER & SIEFFERT, P.A.   Name: Jessica H. Kwak
1625 Radio Drive, Suite 300   Reg. No.: 58,975
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102